

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Mindfulness Based Relapse Prevention Model on Spiritual Health, Quality Of Life and Relapse Prevention in Opioid dependent Patient

Protocol summary

Summary

Objectives: This study aimed to compare the effectiveness of Mindfulness based relapse prevention (MBRP)) on Impulsivity, Distress Tolerance and Relapse Prevention in Opiates dependent Patient at Qom. (2) **Design:** General plan of this study is consisted of experimental pre-test and post-test with follow-up period. (3) **Setting and conduct:** seventy subjects of opiates user who Beyond the period of detoxification and were able to complete the program were selected by convenient sampling and were randomly assigned in two groups (MBRP). Participants in two groups filled out Barratt Impulsiveness Scale-11scale, Simons JS, Gaher Distress Tolerance Scale questionnaire as pre-test and post- test and two month after intervention. The data were analyzed by SPSS-15 using the Multivariate Analysis of Covariance (MANCOVA). (4) **Participants** including major eligibility criteria: Inclusion criteria: Beyond the period of detoxification ; cycle degree; Age 20-40 years; at least once history of relapse; referred by a psychiatrist (diagnosis of drug dependence) based on DSM-IV; After more than a week of successful detoxification. Exclusion criteria: use Anti-psychotic drugs; having a long-term dependency on a substance simultaneously; the absence of more than two session; Get a history of other therapy during the past month. (5) **Interventions:** The intervention is consisted of 8 sessions (each session is 120 minutes) of Mindfulness based relapse prevention for the experimental group. (6) **Main outcome measures:** Main outcome measures variables in this research are Spiritual Health, Quality Of Life and Relapse Prevention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042825870N4**

Registration date: **2016-05-06, 1395/02/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-06, 1395/02/17

Registrant information

Name

Mehdi Yaghobi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-08-04, 1393/05/13

Expected recruitment end date

2015-09-04, 1394/06/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Mindfulness Based Relapse Prevention Model on

Spiritual Health, Quality Of Life and Relapse Prevention in Opioid dependent Patient		Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan, Iran	
Public title	Effect of Mindfulness Based Relapse Prevention Model on Spiritual Health, Quality Of Life and Relapse Prevention in Opioid dependent Patient	City	Kashan
Purpose	Prevention	Postal code	
Inclusion/Exclusion criteria	Inclusion criteria: Beyond the period of detoxification ; cycle degree; Age 20-40 years; at least once history of relapse; referred by a psychiatrist (diagnosis of drug dependence) based on DSM-IV; After more than a week of successful detoxification. Exclusion criteria: use Anti-psychotic drugs; having a long-term dependency on a substance simultaneously; the absence of more than two session; Get a history of other therapy during the past month inclusion criteria: Beyond the period of detoxification ; cycle degree; Age 20-40 years; at least once history of relapse; referred by a psychiatrist (diagnosis of drug dependence) based on DSM-IV; After more than a week of successful detoxification. Exclusion criteria: use Anti-psychotic drugs; having a long-term dependency on a substance simultaneously; the absence of more than two session; Get a history of other therapy during the past month	Approval date	2015-06-05, 1394/03/15
Age	From 20 years old to 40 years old	Ethics committee reference number	IR.KAMUS..RES.1394.45
Gender	Male	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	No information	Description of health condition studied	
Sample size	Target sample size: 70	opioid dependency	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
Randomization description		F11	
Blinding (investigator's opinion)	Not blinded	ICD-10 code description	
Blinding description		F11 Mental and behavioral disorders due to use of opioid	
Placebo	Not used	Primary outcomes	
Assignment	Parallel	1	
Other design features		Description	
Secondary Ids		Spiritual Health	
empty		Timepoint	
Ethics committees		before intervention, After intervention, 1 month after intervention	
1		Method of measurement	
Ethics committee		Ellison Spiritual Well-being(SWB)	
Name of ethics committee		Secondary outcomes	
Ethics committee of Kashan University of Medical Sciences and Health Services		1	
Street address		Description	
		Quality Of Life	
		Timepoint	
		Before intervention, After intervention, 1 month after intervention	
		Method of measurement	
		Quality Of Life scale(SF36)	
		Intervention groups	
		1	
		Description	
		Mindfulness Based Relapse Prevention; 8 sessions; 2 hours, intervention group	
		Category	
		Behavior	
		Recruitment centers	
		1	
		Recruitment center	

Name of recruitment center

Apadana Methadontherapy Institu

Full name of responsible person

Mosavi panah hossein

Street address

Apadana Methadontherapy Institue,Doctors spetialist bulding,kamal almolk sq,Kashan,Iran.

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City

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Full name of responsible person

Dr Qolam Ali Hamidi

Street address

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

City

Kashan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Mehdi Yaghobi

Position

M.Sc Candidate in Clinical Psychology

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Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty